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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,791	07/25/2003	Steve Bigus	ACS 64940 (2238D)	2675

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FULWIDER PATTON
6060 CENTER DRIVE
10TH FLOOR
LOS ANGELES, CA 90045

EXAMINER	
ISABELLA, DAVID J	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 12/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,791	BIGUS ET AL.	
	Examiner	Art Unit	
	DAVID J. ISABELLA	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-11 and 20-34* is/are pending in the application.

4a) Of the above claim(s) *8-10,22,23 and 31-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-7,11,20,21 and 24-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

The Amendment filed 6/29/2006 has been entered. The changes to the specification and claims have been approved by the examiner. Claims 2-4 and 12-19 have been canceled, and claims 8-10,22,23,31-34 have been withdrawn from consideration as being directed to non-elected species. Furthermore, with respect to claim 25 and claims 26-30 dependent therefrom, these claims have been removed from consideration as being drawn to non-elected species. (See examiner's explanation in the arguments set forth in the specification below.) Accordingly,claims 1,5-7,11,20,21 and 24 are pending for consideration.

Specification

The specification was objected to as failing to provide proper antecedent basis for the claimed subject matter and correction of the following was required: claim 1 requires that the "biocompatible material is configured to fail at an inflation pressure *below the nominal inflation pressure of the expandable member*" (italicized for emphasis). According applicant's arguments, the specification page16, lines 15-19 does support the language of the claims. Accordingly, the objection to the specification has been vacated.

The specification was also objected to as failing to provide proper antecedent basis for the claimed subject matter of new claim 25. Claim 25 requires that the

filament be wrapped around and heat bonded to the stent "such that it does not overlie the distal end and the proximal end of the stent". Applicant argued that this feature is supported as illustrated in figure 1 and the specification, page 10, lines 4-5. Examiner disagrees with applicant arguments.

The examiner objected to the antecedent basis for the claimed subject matter of new claim 25. Applicant respectfully submits that this limitation is indeed supported by the specification at page 10, lines 4 - 5, to wit: "In the embodiment of FIG. 1, the sheath 16 is longitudinally shorter than the stent 14." It follows then that the sheath or filament in this embodiment is shorter than the length of the stent, and the sheath or filament does not overlie the distal and proximal ends of the stent.

The applicant has no basis, support or evidence for the assertion of "it follows that the ***sheath or filament*** in this embodiment is shorter". Since figures 9 and 10 are directed to the filaments and not the sheath, such statement is without merits.

Because this limitation was claimed in a preliminary amendment filed on date with the application and is supported by a broad interpretation of Figures 9 and 10, it is not considered new matter. However, it must now be included into the specification. Claims 25-30 receive priority benefit of parent application 09/897,743 and have an effective filing date of June 29, 2001.

Response to Arguments

Applicant's arguments filed 6/29/2006 have been fully considered but they are not persuasive.

Examiner agrees that applicant has support for the language of the "biocompatible material is configured to fail at an inflation pressure *below the nominal inflation pressure of the expandable member*" (italicized for emphasis). Accordingly, applicant has priority dating back to June 29, 2001. However with respect to claim 25, examiner disagrees with applicant's arguments and conclusions regarding the claimed feature; and the effective priority date for claims 25-30 would be applicant's filing date of this application.

With respect to Lenker, applicant has alledged that Lenker '161 is not prior art, in that it does not appear that the teachings relied on by the examiner is present in the parent application. Examiner respectfully disagrees with applicant interpretation of Lenker 6878161 which has priority back to Lenker 5843158. The subject matter relied upon in '161 is fully disclosed in Lenker'158. Applicant's attention is directed to columns 4,5,7,9,12 and 14. Accordingly, Lenker has an effective date back to February 6, 1996.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5, 6, 11 and 24 rejected under 35 U.S.C. 102(e) as being anticipated by Lenker (USPN 6,878,161).

Lenker ('161) discloses a catheter assembly for delivering an endoprosthesis within a body lumen with all the elements of claim 1. See Figures 1A-2C for a catheter (126) and an endoprosthesis (110) disposed on an expandable member (125). See Figure 1A and column 6, lines 17-31 and 65-67 for a biocompatible material (123) being positioned on the endoprosthesis (110) and preventing expansion of the endoprosthesis (110). See column 7, lines 4-20 for the biocompatible material (123) being configured to fail at an inflation pressure below the nominal inflation pressure of the expandable member (125).

Claim 5, see Figure 1A and column 6, lines 20-22 for the biocompatible material (123) comprising a filament that is wrapped around at least a portion of the endoprosthesis (110).

Claims 6 and 11, see Figure 1A and column 6, lines 20-22 for the endoprosthesis having an open lattice configuration with open areas, and the filament being threaded through the open areas. At least a portion of the filament is therefore positioned within the open areas.

Claim 24, see column 5, lines 58-67 for the endoprosthesis comprising a self-expanding stent. See Figure 1A and column 6, lines 65-67 for the biocompatible material (123) providing an inward pressure on the stent to prevent expansion of the stent.

Claims 25, 26, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lenker et al. (USPN 5,843,158).

Lenker et al. ('158) disclose an endoprosthesis for deployment in a body lumen with all the elements of claim 25. See Figures 5B-5D and column 9, lines 36-53 for a stent (100) and a biocompatible material comprising a filament (102) wrapped around and heat bonded (column 9, lines 44) to the stent (100) such that it does not overlie the distal and proximal ends of the stent (100) and prevents expansion of the stent (100).

Claim 26, see column 9, line 44 for tying of the filament (102), which comprises feeding the filament through the open areas.

Claim 29, See Figures 5-5D for the stent (100) having an open-lattice structure.

Claim 30, see column 8, lines 42-43 for the frame rings (72) making up the stent (100) being self-expanding. See column 4, lines 20-25 and column 9, lines 39-42 for the filament (102) providing inward pressure on the stent (100) to prevent expansion of the stent (100).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker ('161) in view of Lenker et al. ('158).

Lenker ('161) discloses a catheter assembly for delivering an endoprosthesis within a body lumen with all the elements of claim 5, but is silent to the filament being heat bonded to the endoprosthesis, as required by claim 7. Lenker et al. ('158) teach a frangible filament (102) that is wrapped around and heat bonded to an endoprosthesis (100) in order to attach the filament to the endoprosthesis. See column 9, lines 42-45. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Lenker et al. ('158) to modify the assembly of Lenker ('161) by having the filament (123) heat bonded to the endoprosthesis (110) in order to attach the filament to the endoprosthesis. The examiner contends that heat bonding will advantageously prevent the filament from becoming detached from the endoprosthesis and becoming loose in the blood stream upon failing.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker ('161) in view of Lenker et al. ('158) and Solar (USPN 5,549,635, as cited in applicant's IDS).

Lenker ('161) discloses a catheter assembly for delivering an endoprosthesis within a body lumen with all the elements of claim 5, but is silent to the filament comprising areas of varying strength along the filament such that the filament fails in a controlled manner, as required by claim 20, and of the areas of varying strength consisting of one of scoring, perforations and thinner diameter portions, as required by

claim 21. Lenker et al. ('158) teach a frangible filament (102) that is wrapped around and heat bonded to an endoprosthesis (100) in order to attach the filament to the endoprosthesis. Solar teaches an endoprosthesis delivering catheter assembly, wherein a biocompatible material (40) is positioned on the endoprosthesis (10) and is configured to fail upon expansion of the expandable member (38). The biocompatible material (40) includes areas of varying strength in the form of perforations (42) in order for the biocompatible material (40) to fail only at those areas with the perforations and prevent the remaining portions of the biocompatible material (40) from being torn away from attachment to the expandable member (38). See Figures 4a-4c and column 6, lines 50-54 and column 7, lines 10-22. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Lenker et al. ('158) and Solar to modify the filament (123) of Lenker ('161) by heat bonding the filament (123) to the endoprosthesis and including perforations. Upon inflation of the expandable member (125), the filament (123) will fail only at those areas with the perforations while the remaining portions of the filament (123) that are heat bonded to the endoprosthesis (110) will be prevented from being torn away and becoming loose in the blood stream.

Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. ('158) in view of Solar.

Lenker et al. ('158) disclose an endoprosthesis for deployment in a body lumen with all the elements of claim 25, but are silent to the filament comprising areas of

varying strength along the filament such that the filament fails in a controlled manner, as required by claim 27, and of the areas of varying strength consisting of one of scoring, perforations and thinner diameter portions, as required by claim 28. Solar teaches an endoprosthesis delivering catheter assembly, wherein a biocompatible material (40) is positioned on the endoprosthesis (10) and is configured to fail upon expansion of the expandable member (38). The biocompatible material (40) includes areas of varying strength in the form of perforations (42) in order for the biocompatible material (40) to fail only at those areas with the perforations and prevent the remaining portions of the biocompatible material (40) from being torn away from attachment to the expandable member (38). See Figures 4a-4c and column 6, lines 50-54 and column 7, lines 10-22. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Solar to modify the filament (102) of Lenker et al. ('158) by including perforations in order for the filament (102) to fail only at those areas with the perforations while the remaining portions of the filament (102) that are heat bonded to the stent (100) are prevented from being torn away and becoming loose in the blood stream.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
12/4/2006